

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
(BROWNSVILLE DIVISION)

BEATRIZ E. EBEL, §
Individually and as §
Personal Representative of the §
Estate of PHILIP WAYNE EBEL, §
Deceased, and as Next Friend of §
ERIC FERNANDO EBEL and §
GABRIELA NICOLE EBEL, Minors, §
Plaintiff, §
§
v. §
§
ELI LILLY AND COMPANY, §
Defendant. §

CASE #: 1:04-cv-00194

PLAINTIFF'S REQUESTED JURY INSTRUCTIONS

Plaintiff asks the Court to give the following instructions to the Jury at the conclusion of the trial, and to submit the case to the Jury on Special Interrogatories in accordance with the attached Verdict Form. Sources of authority for each instruction are included in a note following the instruction, but are not restated on the Verdict Form.

Instruction No. 1 - Theories of Liability

Plaintiff Beatriz Ebel has made four different legal claims against Defendant Eli Lilly in this case. To prevail in this lawsuit she must prove one or more of the claims by a “preponderance” of the evidence. The legal theories or claims are as follows. First, Ms. Ebel claims that Lilly is liable under Texas products liability law for marketing a product, *i.e.*, Zyprexa, which is “defective” and “unreasonably dangerous” because of Lilly’s failure to include legally adequate warnings and instructions about the risk that Zyprexa could trigger a person to commit suicide. Second, she also contends that Lilly’s marketing was done in an unreasonable or “negligent” way. Third, she contends that Lilly is also liable under a breach of warranty theory because its product contained a “defect” which made it unreasonably dangerous for Philip Ebel’s use. Finally, she contends that Lilly is liable because of material misrepresentations made in connection with the marketing of Zyprexa.

Mrs. Ebel claims that Lilly’s product and its conduct were the legal causes of the death of her husband, Philip Ebel. As I will explain in a minute, the burden of proof regarding causation is different with respect to different theories of liability.

Lilly denies that any claimed condition of the Zyprexa made the product defective or unreasonably dangerous, and denies that it made any material misrepresentations or overpromoted with regard to the marketing of Zyprexa. Lilly further denies any claimed condition of Zyprexa was a cause of Philip Ebel’s death. Lilly also denies that Beatriz Ebel sustained damages to the extent claimed herein.

Instruction No. 2 – Products Liability for “Defectively Marketed” Products

Beatriz Ebel claims that Philip Ebel was injured and died as a result of his use of the drug Zyprexa, and that there existed in the Zyprexa at the time it left the control of Lilly a “defect,” or condition, which made the drug “unreasonably dangerous” in that the drug was associated with an increased risk of suicide and Lilly failed to give legally adequate warnings and instructions regarding this risk. Beatriz Ebel further claims that the foregoing defective and unreasonably dangerous condition was a “producing cause” of Philip Ebel’ death. “Producing cause” means an efficient, exciting, or contributing cause that, in a natural sequence, produces the injury or harm. Producing cause does not require a finding that the harm was foreseeable to Lilly. There may be more than one producing cause.

Authority: Tex. PJC §§71.5 (marketing defect) and §70.1 (producing cause). *See Rourke v. Garza*, 530 S.W.2d 794, 801 (Tex. 1975). There is no instruction regarding the rebuttable presumption of adequacy because, under the law, once evidence is adduced and/or the Court has determined that one of the statutory rebuttals exists, the presumption “disappears.” *See Ackermann v. Wyeth Pharmaceuticals*, 471 F.Supp.2d 739 (E.D.Tex. 2006), appeal pending.

Instruction No. 3 – Negligence

Beatriz Ebel also claims that Eli Lilly was “negligent” and that its negligence was a “proximate” cause of Philip Ebel’s injuries and death. Negligence means doing that which an ordinarily prudent company would not do, or failing to do, that which an ordinarily prudent company would do, under the same or similar circumstances. In this case, Ms. Ebel contends that Lilly’s negligence includes a failure to test Zyprexa with regard to the dangers of akathisia and suicide, a failure to include legally adequate warnings and instructions regarding these risks, and overpromotion of Zyprexa for “off-label” or unapproved uses. For such negligence to constitute a “proximate cause,” Plaintiff must prove that Eli Lilly’s conduct, in a natural and continuous sequence, produced her husband’s death, and that without such negligence this event would not have occurred. In order to be a “proximate cause,” the act or omission complained of must be such that a person using ordinary care would have foreseen that the event, or some similar event, might reasonably result therefrom. There may be more than one proximate cause of an event.

Authority: Tex. PJC §§2.1 (negligence) and §70.2 (proximate cause).

Instruction No. 4 – Strict Liability for Material Misrepresentations

Finally, Beatriz Ebel claims that Philip Ebel was injured and died as a result of Lilly's material misrepresentations to the medical profession made in conjunction with its marketing of Zyprexa. Lilly is liable under this theory if it made a misrepresentation of a material fact and if Dr. Nett relied on same in prescribing the Zyprexa for Philip Ebel. A "material fact" is a fact that is important to a normal physician or by which the physician may justifiably be expected to be influenced in making the decision to prescribe the drug. To establish liability under this theory, Ms. Ebel must prove that the misrepresentation was a "producing cause," as that term has previously been explained to you.

Authority: Tex. PJC §§71.6 (marketing defect), originally recognized in *Crocker v. Winthrop Laboratories*, 514 S.W.2d 429 (Tex. 1974).

Instruction No. 5 – Breach of Implied Warranty

The law presumes that products are fit for the ordinary and particular purposes for which they are intended. A company that markets a product with a “defect” or with an impurity, breaches that warranty. A “defect” means a condition of the product that renders it unreasonably dangerous. An “unreasonably dangerous” product is one that is dangerous to an extent beyond that which would be contemplated by the ordinary user of the product, with ordinary knowledge common to the community as to the product’s characteristics. To establish liability for a breach of implied warranty, Ms. Ebel must prove that the alleged defect was a “proximate cause,” as I have already defined that term for you, of her husband’s death.

Source: Tex PJC §71.3. In *Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 665 (Tex. 1999) the Supreme Court held that the essential, ultimate factual inquiry with regard to breach of warranty claims, is the same as that regarding strict liability, i.e. whether there was a “defect.” The PCJ formulation of “defect” is stated in the classic Restatement language, i.e. employing a “consumer expectation” test with regard to a product’s defects.

Instruction No. 6 - Sole Cause and Aggravations of Preexisting Conditions

Lilly has claimed that some other cause was the “sole cause” of Mr. Ebel’s death. As I have instructed you, there may be more than one producing or proximate cause of an event. But if an act or omission of anyone who is not a party to the suit was the “sole cause” of the injury and death, then the act or omission of Lilly, or of its drug Zyprexa, could not have been a cause of Philip Ebel’s death. Lilly has the burden of proof to establish such “sole cause.”

Sometimes, one cause aggravates a preexisting condition. If you find that to be the situation here, then you would award damages only to the extent that such other condition was aggravated by the Zyprexa in this case.

Source: Tex PJC §70.4 (sole cause) and §80.8 (aggravation of preexisting condition).

Instruction No. 7 - Learned Intermediary Doctrine

The manufacturer of a product has a duty to adequately warn and instruct about the dangers of its product. However, because the Zyprexa involved in this case can only be obtained with a prescription from a physician, the manufacturer Lilly ordinarily has a duty to adequately warn only the prescribing physician, Dr. Nett, about the risk of harm. Ordinarily, Lilly has no duty to warn the patient directly.

However, there is an exception to this rule. If you find from the evidence that "Lilly either knew, or had reason to know, that Philip Ebel's health-care providers would not be in a position to reduce the risks of harm in accordance with the instructions or warnings," then Lilly would have a duty to warn the patient directly.

Source: The first paragraph states the learned intermediary doctrine. The second is taken directly from the RESTATEMENT (THIRD). See authorities and discussions in Plaintiff's Brief opposing Lilly's MSJ on learned intermediary grounds. The Court should also decide whether "overpromotion" is a question of fact for the jury or of law for the Court.

Instruction No. 8 – FDA Warning Requirements

With respect to prescription drugs, there are also certain federal regulatory requirements or duties regarding written warnings in the package label or insert. These regulations require a description of serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling must be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. Special problems, particularly those that may lead to death or serious injury, may be required to be placed in a prominently displayed box. If a boxed warning is required, its location will be specified by the FDA.

These FDA regulations establish minimum safety standards. Therefore, if you decide that Lilly violated this federal regulation, then you may consider that fact together with all other facts to determine whether Lilly violated its duty to warn under Texas law.

Source: This instruction was given in the recent Effexor/suicide trial of *Giles v. Wyeth*. Authority includes 21 C.F.R. § 201.57(e) and a host of cases establishing that FDA regulations are only “minimum” in nature. E.g., *Graham v. Lilly Laboratories*, 906 F.2d 1399, 1405 n.9 (10th Cir. 1990), *aff’g*, 666 F.Supp. 1483, 1489-94 (D. Kan. 1987); *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F.Supp.2d 1018, 1036 (S.D.Ill. 2001), and other cases cited in FN 17 of Plaintiff’s Brief in Opposition to Lilly MSJ.

Instruction No. 9 - Heeding Presumption

Presumptions are rules based upon experience or public policy and are established in the law to assist a jury in discovering the truth. Presumptions take the place of evidence unless and until outweighed by evidence to the contrary.

Where an adequate warning is given, the manufacturer may reasonably presume that it will be read and that the product will be used according to the directions or instructions. A product bearing such a warning, which is safe for use if it is followed, is not defective, nor is it unreasonably dangerous. On the other hand, where no warning is given, or where there is an inadequate warning, the law presumes that, if an adequate warning had been given, that it would have been read and heeded and that the risk of harm would thereby have been avoided.

Source: There is no pattern instruction. This presumption has been thoroughly briefed in conjunction with Lilly's Motion for Summary Judgment.

Instruction No. 10 – Proportionate Responsibility

Lilly is only liable with regard to its proportionate percentage of legal responsibility. In this case, it is making two claims with regard to the fault of others. First, it claims that Philip Ebel was negligent. Philip Ebel's negligence would reduce his family's recovery. However, in assessing his negligence, you are instructed not to consider any act or omission of Philip Ebel that constitutes a mere failure to discover or guard against a product defect. Second, Lilly claims that GlaxoSmithKline, and its drug Paxil, may have also contributed. The parties agree that GSK has previously settled Ms. Ebel's claims against it. Lilly bears the burden of proof to establish to what degree, if at all, either Mr. Ebel or GSK/Paxil were at fault. You must make any percentage determination asked of you from a preponderance of the evidence.

Source: TCPRC, §33.003, 33.011; Tex PJC §71.2, 71.12, and comment thereto.

Instruction No. 11 – Wrongful Death Damages

If Plaintiff Beatriz Ebel prevails on one or more of her theories of liability, you must assess reasonable damages for the wrongful death of Philip Ebel, both to Mrs. Ebel, as his widow, and to his children. In determining such damages, you may consider the following items:

- a. Pecuniary loss sustained in the past and which, in reasonable probability, will be sustained in the future. “Pecuniary loss” means the loss of the care, maintenance, support, services, advice, counsel, and reasonable contributions of a pecuniary value, excluding loss of inheritance, that Beatriz Ebel and her children Eric Fernando Ebel and Gabriela Nicole Ebel in reasonable probability, would have received from Philip Ebel had he lived.
- b. Loss of companionship and society sustained in the past and future. “Loss of companionship and society” means the loss of the positive benefits flowing from the love, comfort, companionship, and society that Beatriz Ebel, and the children, would in reasonable probability, have received from Philip Ebel had he lived.
- c. Mental anguish – past and future. “Mental anguish” means the emotional pain, torment, and suffering experienced by Beatriz Ebel and the children because of the death of Philip Ebel.
- d. Loss of inheritance. “Loss of inheritance” means the loss of the present value of the assets that the deceased, in reasonable probability, would have added to the estate and left at natural death to Beatriz Ebel and/or his children.

Source: Tex PJC §81.3-.4

Instruction No. 12 – Survival Damages for Philip Ebel’s Estate

If Plaintiff Beatriz Ebel prevails on one or more of her theories of liability, you must assess reasonable damages for the Estate of Philip Ebel. In determining such damages, you may consider the reasonable funeral and burial expenses as well as any conscious physical pain and emotional pain, torment, and suffering experienced by Philip Ebel before his death as a result of his ingestion of Zyprexa.

Source: Tex PJC §82.3.

Instruction No. 13 – Standards for Imposing Exemplary Damages

The Texas Constitution provides that, if a party's "gross negligence" results in the wrongful death of another, then that party may be punished by an assessment of punitive or "exemplary" damages. "Gross negligence" means an act or omission by Eli Lilly (a) which when viewed objectively from the standpoint of Eli Lilly at the time of its occurrence involves an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and (b) of which the company had actual, subjective awareness of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others. Such gross negligence must be established by "clear and convincing evidence," which means the measure or degree of proof that produces a firm belief or conviction of the truth of the allegations sought to be established.

Source: Tex PJC §85.1C.

Instruction No. 14 – Determining Amount of Exemplary Damages

“Exemplary damages” means any damages awarded as a penalty or by way of punishment but not for compensatory purposes. Exemplary damages includes punitive damages. In determining the amount, if any, of such damages, you may consider the following:

- a. the nature of the wrong;
- b. the character of the conduct involved;
- c. the degree of culpability on the part of Eli Lilly;
- d. The situation and sensibilities of the parties concerned;
- e. The extend to which such conduct offends a public sense of justice; and
- f. Eli Lilly’s net worth.

Source: Tex PJC §85.3C.

VERDICT

LADIES AND GENTLEMEN OF THE JURY. Please render your verdict in this case, in accordance with the instructions that I have given you, by providing specific answers to the following questions. Your answers must be unanimous.

Question No. 1

Was the Zyprexa taken by Philip Ebel “defective” and “unreasonably dangerous” because of Eli Lilly’s failure to provide legally adequate warnings and instructions about the potential risk of Zyprexa-induced suicidality to either Dr. Nett and/or to Philip Ebel, and, if so, was such condition a “producing cause” of Philip Ebel’ death?

Answer “Yes” or “No” separately, as to each.

a) Dr. Nett _____

b) Philip Ebel _____

Question No. 2

Was Eli Lilly negligent and, if so, was such negligence a proximate cause of Philip Ebel's death?

Answer "Yes" or "No."

Answer: _____

Question No. 3

Did Eli Lilly use material misrepresentations to market the Zyprexa in question, and, if so, were such misrepresentations a producing cause of Philip Ebel' death?

Answer "Yes" or "No."

Answer: _____

Question No. 4

Did Eli Lilly breach an implied warranty by marketing a product with a “defect,” and, if so, was such breach a proximate cause of Philip Ebel’ death?

Answer “Yes” or “No.”

Answer: _____

If you have answered "Yes" to Questions 1, 2, 3 or 4, and only in that event, then proceed to answer the following question.

Question No. 5

What sum of money do you assess against Eli Lilly for its proportionate percentage of the responsibility for the wrongful death of Philip Ebel, and in favor of each of the following members of Mr. Ebel's family?

Answer in dollars and cents with respect to each of the following:

Beatriz Ebel (widow) _____

Eric Fernando Ebel (son) _____

Gabriela Nicole Ebel (daughter) _____

If you have answered “Yes” to Questions 1, 2 3 or 4, and have awarded monetary damages in response to Question No. 5, and only in that event, then proceed to answer the following question.

Question No. 6

Do you find from clear and convincing evidence that the harm to Philip Ebel resulted from gross negligence, as that term has been defined for you.

Answer “Yes” or “No.”

Answer: _____

If you have answered "Yes" to Question No. 6, and only in that event, then proceed to answer the following question.

Question No. 7

What sum of money do you assess against Eli Lilly, and in favor of each of the following persons, as exemplary damages for the wrongful death of Philip Ebel?

Answer in dollars and cents with respect to each of the following:

Beatriz Ebel (widow) _____

Eric Fernando Ebel (son) _____

Gabriela Nicole Ebel (daughter) _____

Certification

The undersigned foreperson of this Jury hereby certifies that the foregoing answers represent the unanimous verdict of the Jury in this case.

Jury Foreperson

Respectfully submitted,

VICKERY, WALDNER & MALLIA, LLP

/s/ Arnold Anderson (Andy) Vickery

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Certificate of Service

I certify that on this 14th day of January, 2008, the foregoing pleading has been electronically filed with the Clerk using the CM/ECF system, which will automatically send email notifications of such filing to the following attorneys of record:

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